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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,777	02/20/2002	Jean-Noel Telles	111380	8868

7590

11/17/2003

Oliff & Berridge
PO Box 19928
Alexandria, VA 22320

EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,777

Applicant(s)

TELLES ET AL.

Examiner

Jeffrey Stucker

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/19/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7,14,16-19 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8,9,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 2-4,10,11,15,20,21 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1648

This Office Action is in response to the Election filed 9/3/03. Applicant elects Group II, mutation 90, with traverse. The traversal is on the grounds that independent claims 1 and 8 are both drawn to methods for testing a biological sample that includes investigating the presence of mutations in the protein sequence of the HIV-2 protease.

Applicant's arguments were persuasive in part. The amendment to claim 6 (Group III) places it with the elected subject matter of Group II. The inventions of Groups I and II will be rejoined. In regards to the argument concerning the probes, Group IV, claims 7 and 14, the assertion that the probes are essential tools for performing at least one embodiment of the methods defined in claims 4 and 11 is not persuasive. The probes are not considered to be essential as evidenced by the fact that they are not recited in the method claims. Further, multiple probes, variations, and complements, are claimed and optionally usable for detecting mutations at AA 90 by known methods. Therefore, Groups I, II, and III, claims 1-6, 8-13, and new claims 15, 20, 21, and 26, will be rejoined and Group IV, claims 7 and 14, will not be rejoined.

The technical feature of the claimed invention is the finding that at least one mutation in HIV-2 protease at positions 10, 45, 46, 54, 64, 84, or 90 conveys resistance to protease inhibitors. Each mutation is distinct from the other mutations and are independent. This is evidenced by the specification as well as the claims which recite each of the mutations in separate claims. Further, there would be an undue burden on the Office to examine all of the mutations because of the large number of sequences which would fall within the scope of the claims. There would be 7 mutations with 20 independent variables at each mutation position.

Art Unit: 1648

Thus, the claims lack unity of invention because the claims do not have a special technical feature. Claims 16-19, and 22-25 are also withdrawn from consideration as being drawn to non-elected mutations. Therefore, claims 7, 14, 16-19, and 22-25 are withdrawn from consideration as being drawn to non-elected inventions and claims 1-6, 8-13, 15, 20, 21 and 26 are examined.

The Restriction requirement is still deemed proper and is therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 6, 8, 9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, 6, 8, 9, 12, and 13 are vague and indefinite because it is not clear what the metes and bounds are of "known methods".

Claim 1 is vague and indefinite because it has no specific method steps.

Claims 1-6, 8-13, 15, and 21 are objected to for containing non-elected subject matter.

Art Unit: 1648

Claims 2-4, 10, 11, 15, 20, 21 and 26 are objected to as being dependant upon rejected claims.

It is noted that claim 7 has no part (a).

The instantly claimed invention is free of the art of record in regards to mutations at position 90. While it is known that HIV-1 protease is resistant to protease inhibitors with a mutation a position 90, it does not appear from the record that HIV-1 protease is highly homologous to HIV-2 protease. Therefore, one would not know, *a priori*, that the mutation in position 90 of HIV-1 would also occur or induce resistance in HIV-2.

During interviews with attorney James Voller, allowable subject matter was indicated. The Examiner was willing to allow claims to rejoined methods of detecting a mutation in the protein or nucleic acid sequence if the claims were limited to the elected mutation at position 90. The Examiner's supervisor, James Housel, also discussed this with attorney Voller.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax number is: (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

Application/Control Number: 09/980,777

Page 5

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center Customer Service representative whose telephone number is (703) 308-0198.

A handwritten signature in cursive script, appearing to read "Jeffrey Stucker".

JEFFREY STUCKER
PRIMARY EXAMINER